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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/632,639      | 07/31/2000  | Jeffrey R. Sampson   | 10992786-1          | 3760             |

7590 10/02/2003

Agilent Technologies  
Legal Department 51UPD  
Intellectual Property Administration  
PO Box 58043  
Santa Clara, CA 95052-8043

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| EXAMINER |
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ZARA, JANE J

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1635

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DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

## Office Action Summary

Application No.

09/632,639

Applicant(s)

Sampton et al

Examiner

Jane Zara

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1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jul 15, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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**DETAILED ACTION**

Claims 1-26 are pending in the instant application.

***Election/Restriction***

The restriction requirement mailed June 10, 2003, Paper No. 5, is hereby vacated.

Applicant argues that no proper reasons have been stated that searching all of the inventions will pose a serious burden on the examiner. Upon further consideration, it appears that the claims are drawn to a single invention and so are being examined in their entirety as set forth in the Office action below.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-19, 21-24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 2-11, in claim 12, lines 2-13, and in claim 24, lines 2-4, the metes and bounds of I) nucleic acid molecules characterized by an ability to hybridize to at least one other nucleic acid molecule, and the metes and bounds of ii) nucleotide precursors with a reduced ability to form base pairs with each other, and iii) nucleotides with an ability to form at least one base

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pair with another nucleotide, wherein the nucleotide precursors have a reduced ability to form a stable hydrogen bonded base pair, cannot be determined. Adequate clarification is requested.

In claims 2, 3, 5, 8 and 9, line 1, the phrase "wherein the step of providing nucleotide precursors" is unclear within the context of the claim (e.g. perhaps inserting --in-- after "wherein" would be remedial).

In claim 11, line 2, the phrase "at least one nucleotide precursors" is unclear (e.g. perhaps replacing "precursors" with --precursor-- would be remedial).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-19, 21-24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of synthesizing nucleic acid molecules with reduced levels of cross hybridization, wherein at least one of the molecules synthesized is characterized by an ability to hybridize to at least one other nucleic acid molecule, and wherein the method comprises providing nucleotide precursors sufficient to synthesize a nucleic acid molecule using a nucleic acid template, which precursors include at least one pair of complementary precursors

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characterized by a reduced ability to form base pairs with each other, and further characterized by an ability to form at least one base pair with another nucleotide, and wherein the nucleotide precursors have a reduced ability to form a stable hydrogen bonded base pair.

The specification and claims do not describe the elements essential to the claimed invention, which elements include those that adequately describe the genus comprising nucleotide precursors with a reduced ability to form base pairs with each other and further characterized by an ability to form at least one base pair with another nucleotide, and which precursors have a reduced ability to form a stable hydrogen bonded base pair. The disclosure does not clarify or indicate what distinguishing attributes are concisely shared by the members of this broad genus. The scope of the claims includes numerous structural variants, and genus is highly variant because a significant number of structural differences between members of the genus is permitted. Concise structural features that could distinguish structures or compounds within the genus from others are missing from the claims and from the instant disclosure. No common structural attributes identify the members of this broad genus from others. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. The specification fails to teach or adequately describe a representative number of species in the genus such that the common attributes of characteristics concisely identifying members of this broad genus, which genus comprises nucleotide precursors sufficient to synthesize a nucleic acid molecule using a nucleic acid template, which precursors include at least one pair of complementary precursors characterized by a reduced ability to form base pairs with

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each other, and further characterized by an ability to form at least one base pair with another nucleotide, and wherein the nucleotide precursors have a reduced ability to form a stable hydrogen bonded base pair. And because the genus is highly variant, the description provided is insufficient. Thus, applicant was not in possession of the claimed genus.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-5, 7-17 and 19-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Vivekananda et al.

Vivekananda et al teach methods and compositions (e.g. kits) comprising synthesizing nucleic acid molecules with reduced levels of cross hybridization (see col. 2, lines 20-65; col. 3, line 44-col. 5, line 67; col. 6, line 62-col. 10, line 31), which synthesizing comprises the polymerization of nucleotide precursors from a DNA or RNA template by an appropriate

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polymerase or transcriptase (see col. 22, line 29-col. 24, line 45), and which nucleotide precursors include 2-aminodeoxyadenosine 5'-triphosphate, 2-thiodeoxythymidine 5'-triphosphate, and inosine triphosphate (see col. 20, line 14-col. 22, line 9), whereby a nucleic acid molecule with reduced levels of cross-hybridization is synthesized.

Claims 1-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Kutuyavin et al.

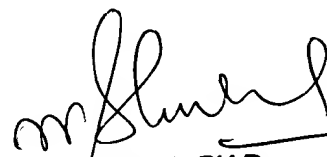
Kutuyavin et al teach methods and compositions (e.g. kits) comprising synthesizing nucleic acid molecules with reduced levels of cross hybridization (see the abstract; col. 2, line 33- col. 9, line 53; claims 1-20, 23-25), which synthesizing comprises the polymerization of nucleotide precursors from a DNA or RNA template by an appropriate polymerase or transcriptase, (see col. 18 and 22-23), and which nucleotide precursors include 2-aminodeoxyadenosine 5'-triphosphate, 2-thiodeoxythymidine or -cytidine, 5'-triphosphate, pyrrolo-pyrimidine triphosphate, inosine triphosphate (see col. 5, col. 34, lines 53- 67), whereby a nucleic acid molecule with reduced levels of cross-hybridization is synthesized (see abstract; text in col. 4; claims 1-20) .

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***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**

***JZ***

October 1, 2003